

II. REMARKS

A. Status of the Claims

Claims 5-9, 11-44, 60-84, and 97-108 were pending in the application at the time of the Office Action, with claims 6-9 and 25-27 having been withdrawn from consideration as being directed to a non-elected invention. Claims 5, 11-17, 20-24, 32-44, 60-62, 64-75, 78, 79, 97-100, and 103-108 have been found to be allowed per the Office Action. *See* page 4, first paragraph.

Claims 18, 19, 28, 77, and 80 have been amended in the Amendment set forth herein without prejudice or disclaimer. Claims 1-4, 6-10, 25-27, 45-59, 63, 76, 81-96, and 101-102 have been canceled without prejudice or disclaimer. No new claims have been added. Thus, claims 5, 11-24, 28-44, 60-62, 64-75, 77-80, 97-100, and 103-108 are currently pending in the case. Applicants concur with the summary of the status of the claims as set forth in the Office Action dated August 13, 2008.

Support for the amendments to the claims is discussed in detail below.

B. The Rejections Under 35 U.S.C. §112, Second Paragraph, Are Overcome

Claims 18-19, 28-31, 76-77, and 80-84 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse.

1. Claim 18

Claim 18 is rejected as being indefinite for reciting, in the alternative, that the adenovirus comprises a tissue-specific promoter or an inducible promoter substituted for the E4 promoter because the term “tissue specific promoter” is not limited to a promoter that drives expression in tumor cells. Without conceding that the Examiner is correct, Applicants note that claim 18 has been amended to recite that the vector comprises a “tumor specific promoter.” Support for this

amendment can be found generally throughout the specification, such as in the claims as originally filed and on page 17, line 36- page 18, line 4 of the specification.

2. Claim 19

Claim 19 is rejected for reciting “wherein the recombinant adenovirus which comprises....” In particular, the word “which” in the claim is said to be a typographical error. Applicants have amended the claim to delete the word “which,” as suggested by the Examiner.

3. Claim 28

Claim 28 is said to be rejected for reciting that “the adenovirus is replication defective, or it is replication-restricted to dividing cells or neoplastic cells” because claim 13, from which it depends, requires that the adenovirus be replication competent. The Examiner indicates that the alternative embodiment where the vector is identified as being replication-restricted to dividing cells or neoplastic cells is not considered indefinite. Without conceding that the Examiner is correct, Applicants note that claim 28 has been amended to omit the alternative that “the adenovirus is replication defective.”

4. Claims 76 and 77

Claim 76 is said to be indefinite for reciting that “the adenovirus is replication defective” because this claim depends from claim 60, which requires that the adenovirus vector be replication competent. Claim 77 is included in this rejection because it depends from claim 76. Without conceding that the Examiner is correct, Applicants note that claim 76 has been canceled without prejudice or disclaimer, and claim 77 has been amended to depend from claim 60 rather than claim 76. Support for the amendment to the claims can be found, for example, in the claims as originally filed.

5. Claims 80-82

Claims 80 and 81 are said to be indefinite for reciting that one alternative for the promoter is a “tissue specific promoter.” Claim 60, from which claim 80 depends, requires expression in neoplastic cells and the Examiner argues that the term “tissue specific promoter” encompasses promoters that drive transcription in non-tumor tissues. Without conceding that the Examiner is correct, Applicants note that claim 80 has been amended to omit the alternative of tissue specific promoter and claim 81 has been canceled without prejudice or disclaimer.

Claim 82 is said to be indefinite for reciting “a transcriptional regulatory element” or a number of specific promoter species, and that therefore the claim covers sequences that modify transcription in tissues other than tumor tissue, as required by claim 60. Without conceding that the Examiner is correct, Applicants note that claim 82 has been canceled without prejudice or disclaimer.

6. Claims 83-84

Claims 83-84 are said to be indefinite in the recitation that the vector comprises an adenoviral gene essential for replication under control of an inducible promoter. The claims are said to lack an essential step that includes administering the inducer to achieve replication competency. Without conceding that the Examiner is correct, and in an effort to expedite receipt of a notice of allowance, Applicants note that claims 83-84 have been canceled without prejudice or disclaimer.

Applicants specifically reserve the right to prosecute of the aforementioned canceled claims or any subject matter canceled from the claims as originally pending in a divisional or continuation application.

In view of the foregoing, claims 18-19, 28-31, 77, and 80 are not indefinite. Therefore, it is respectfully requested that the rejection of these claims under 35 U.S.C. §112, second paragraph, be withdrawn.


C. The Objection of Claim 63 is Moot

Claim 63 is objected to under 37 C.F.R. §1.75 as being a substantial duplicate of claim 15. Applicants have canceled claim 63 without prejudice or disclaimer. Therefore, the objection of claim 63 is moot.

D. Conclusion

In view of the foregoing, it is respectfully submitted that all of the pending claims are in condition for allowance, and a Notice of Allowance is earnestly solicited. The Examiner is invited to contact the undersigned attorney at (512) 536-5639 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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